

**Kaiser Permanente Testimony for the National Committee on Vital and
Health Statistics Regarding the HIPAA Consent Requirement
- Mary Henderson, National HIPAA Program Director -
August 21, 2001**

Good afternoon. My name is Mary Henderson and I am the National HIPAA Program Director for Kaiser Permanente. Thank you for inviting me to speak today about the "HIPAA consent" requirement.

Since I have only 10 minutes, and this is a complex issue, I have included additional testimony in writing.

Kaiser Permanente is comprised of three organizations – Kaiser Foundation Health Plan, Kaiser Foundation Hospitals, and Permanente Medical Groups. These three organizations cooperate to provide coverage and medical services to members within each of our eight Regions. In each Region, Health Plan contracts with a Permanente Medical Group to provide medical care to members. As a highly integrated healthcare system, we believe that we fit the description of an Organized Health Care Arrangement and would need to seek a joint consent for our health plans and providers.

Kaiser Permanente strongly supports the overall goals of HIPAA Administrative Simplification. However, some provisions in the Privacy Rule – most notably the HIPAA consent requirement – will create unintended but significant barriers to the delivery of health care services to our 8.2 million members.

My objective today is to share with you some situations in which the HIPAA consent requirement impedes effective and efficient health care delivery and has effects contrary to the intent of HIPAA.

Given these impacts:

- **We strongly urge that DHHS delete the consent requirement.**
- **Barring that, we ask DHHS, at a minimum, to mitigate the unintended negative consequences to patient care and health care delivery.**

In the Proposed Rule DHHS noted the questionable validity of a blanket authorization, which is what HIPAA consent is. They determined that it would be neither voluntary nor truly informed. We believe that conclusion was correct then, and that it is correct now.

Consent, that is informed and voluntary, is a positive and powerful principle in health care and a core value at Kaiser Permanente. However, HIPAA consent does not provide patients a truly informed and voluntary choice. In medical care "informed consent" means giving a patient sufficient information prior to receiving treatment, and giving them a choice about what is done. A patient could consider and decide: "Should the surgeon do my prostate surgery using a scalpel or a laser?" "Should I agree to a radical mastectomy, or consider another option?" These are meaningful choices.

Consent, as that term is used in the Final Rule, provides no such opportunity.

Let me remind you that the Rule already has meaningful tools that protect an individual's medical privacy, including:

- precise limits on the allowable uses and disclosures of PHI (protected health information),
- notice,
- specific written authorizations for other uses, and
- sanctions for misuse.

The HIPAA consent requirement adds nothing to these protections, provides no real value to patients because the consent is neither knowing nor voluntary, and can actually cause harm.

A stated goal of HIPAA Administrative Simplification is to improve the efficiency and effectiveness of the health care system by encouraging the development of electronic health information systems. Ironically, HIPAA consent is likely to be easiest to implement by a single site health care provider who uses only paper records. Such providers would have only one, or at most a few places, to check whether a patient has an unrevoked consent on file. For larger organizations, particularly those with multiple sites of care, numerous electronic systems, along with paper records in many locations, the process of obtaining HIPAA consent, and then storing, tracking and updating it to reflect revocations, is mind-boggling.

I am actively involved with the implementation of the Privacy Rule as Kaiser Permanente's national HIPAA director. Let me share with you, some of the challenges I see HIPAA consent posing, not just for our health care operations but also for our members when they try to secure care.

We are faced not only with getting consent from our 8.2 million current members, but getting consent from up to 35 million former members. Many have moved away. Some have died. We have no way to reach them. Yet their medical information is woven throughout our systems.

Currently for the majority of our members, we have not obtained blanket authorizations because state law has provided statutory authorization.¹ Most of our members enroll through their employers with no direct contact with us. In states where blanket authorization is currently required we obtain it solely from the subscriber and not from anyone else in the family.

To obtain HIPAA consent, our members, their employers and Kaiser Permanente would all have to be involved in complex new layers of paperwork and process. This is a step backward from HIPAA's efforts to encourage effective use of technology. Our members

¹ Statutory Authorization: the authority for certain persons to use or disclose protected health information for specific limited purposes.

heavily rely upon our phone and internet appointment and advice services. Under HIPAA consent they would be blocked from being able to use these health care technologies until they sign a consent.

HIPAA consent poses a formidable barrier to continuing health care operations. No health care information in our systems can be lawfully used until consent is obtained; yet we have no practical way to segregate the data for members who have consented from those who have not. The consequences for us, and we assume for other health care systems, are substantial. All existing data would have to be either blocked or archived. Please consider the effects this would have on quality review, provider credentialing, planning, evaluation of drugs and medical devices, and even emergency treatment.

The right to revoke consent causes additional problems. Patient data is integrated into our systems with no reasonable way to extricate it. We rely upon it for essential health care operations. Furthermore, if a member withdraws consent from a Permanente Medical Group, Health Plan will have to disenroll that member. This creates a real catch-22 for us. HIPAA Portability provisions generally preclude disenrollment of any member except for nonpayment or fraud. Which part of HIPAA should we follow?

The HIPAA consent requirement will place us in many moral and ethical dilemmas. Let me give you examples. A couple of years ago we were notified by a drug company that a batch of their epinephrine solution was contaminated. Epinephrine is carried by severely allergic patients at high risk of anaphylactic shock, which is life threatening. We were able to go into our systems, identify all 2,350 patients at risk, and provide them new medication very quickly. Under HIPAA consent what would have happened to those patients who had not yet signed a consent, or who had revoked consent?

What if a patient revokes consent, and later is brought into our ER in a coma. We will, of course, do our very best to treat them. But if their critical medical information is blocked or archived how can we be sure that we aren't administering a medication that the patient is allergic to? This, too, has life threatening implications.

Given these serious issues, we make the following recommendations:

- **First and foremost – we strongly urge that DHHS rescind the HIPAA consent requirement and return to the soundness of the proposed rule.**

Barring that, we recommend these seven measures to help lessen the negative impact of the HIPAA consent requirement.

- Allow continued use of the data collected before the April 14, 2003 compliance deadline and require consent only for data collected after that date.
- Allow use and disclosure of data collected before revocation for continuing TPO (treatment, payment, and health care operations).

- Allow the continued use of data until a patient makes a physical appearance and is able to sign a consent form.
- Make the HIPAA consent requirement inapplicable to states that have statutory authorization for the use and disclosure of PHI.
- Defer the consent requirement for five years. Then assess whether the other HIPAA tools provide adequate protection.
- Reconcile conflicting laws, such as those that do not permit disenrollment upon the revocation of consent.
- Rely on parental consent for a child who reaches the age of majority until that new adult comes in for care.

We urge the Committee to carefully review the problems posed by the HIPAA consent requirement and to recommend to DHHS that it return to the position it took in the proposed rule. Rescind HIPAA consent. It adds enormous barriers to the delivery of health care without providing meaningful choice or protection for our patients.

Thank you.

APPENDIX

Kaiser Permanente Examples: Operational Challenges of Implementing HIPAA Consent

The HIPAA written consent requirement will cause significant problems in the day-to-day operation of health care systems by creating serious, if unintended, barriers to the delivery of appropriate and timely health care services.

Revoked HIPAA Consents Place Necessary Treatment at Risk

In the spring of 2000, Kaiser Permanente pharmacy staff received an FDA notice alerting them to a potentially life-threatening interaction between two drugs. These two drugs, when prescribed to depressed patients, actually increased the chances of suicide. We queried our pharmacy data system to identify every patient who had received the potentially lethal two-drug combination. Concurrently, we queried the clinical information system to identify patients not found on the pharmacy data system, but who had received prescriptions for the drugs. Finally, the two databases were matched to identify treating physicians, who then quickly notified the affected patients instructing them on appropriate courses of action. Our ability to identify and contact the affected members is attributable to the potent combination of robust clinical information systems and a highly integrated health care delivery system. Had we been faced with a situation in which members had revoked their HIPAA consents, we would have been unable to avert a potentially tragic outcome.

On August 15, 2001 a non-Kaiser Permanente Kansas City pharmacist was arrested for dispensing diluted cancer prescriptions. If this was discovered today at one of the pharmacies with whom Kaiser Permanente contracts, it would be possible to identify all patients who received such medications, contact them, and encourage them to visit a doctor for evaluation. Any of this patient population who revoked HIPAA consent for general purposes could not be identified and contacted for such a specific purpose critical to their health condition.

The New York Times reported on August 16, 2001 that a Philadelphia hospital laboratory "used the wrong form of chemical in conducting a routine blood test, leading hundreds of patients to receive incorrect doses of a blood-thinning medicine, and possibly causing five deaths." The hospital laboratory identified a seven-week time period in June and July during which patients were given the erroneous doses of medicine. In our current environment, Kaiser Permanente members could have been identified and promptly notified of the mix-up. Under HIPAA, patients who revoked their HIPAA consent following receipt of their medicine could not be identified or contacted, thus potentially endangering their lives.

Obtaining HIPAA Consent Introduces a Complex and Costly Burden

New and current members

Obtaining HIPAA consent from Kaiser Permanente's current members will be difficult to achieve. Introduction of written forms to an ever-increasing use of electronic enrollment is not a viable option. Most new enrollment and renewal of membership is accomplished between employees and employers, often with enrollment information submitted to Kaiser Permanente by the employer electronically. While mail campaigns to members and their dependents could be conducted, a low response rate is expected. Obtaining HIPAA consent would probably need to occur during visits to medical offices or emergency rooms or admissions for hospital care. Adding just one minute to the average time to register for a medical office visit will substantially increase staff workload and wait times for our members. For example, Kaiser Permanente providers in California deliver care for approximately 25 million member visits per year, and a minute added to each visit registration would roughly equal 420,000 hours of new staff workload that would need to be supported in California alone. Our ability to provide customer service will be greatly restricted by the additional time spent obtaining and verifying members' consent status. This will only serve to frustrate and annoy our members.

Unemancipated minors cannot legally consent to use or disclose their protected health information until they reach the age at which they have authority to act as an individual. In most states they must be at least 18 years old, though for some specific sensitive services such as mental health care or family planning they may secure the right to consent to receive services and control the use and disclosure of their health information at an earlier age. At the point they reach the age where they have the authority to act as an individual, however, any consent signed by their parents or guardian will no longer be valid. That means that neither a provider nor a plan can use the medical information of a member who was previously a minor for treatment, payment or health care operations until a HIPAA consent is secured – even where the member has been a patient of a physician, or a member of a plan, since birth.

Former members

Kaiser Permanente has a 55-year history with a relatively stable member population – with many who remain members throughout their lifetimes. This enables us to maintain records over long periods of time to improve care and service, prevent illness, conduct quality assurance and research, and plan for future facility and medical professional needs. We are currently expanding our electronic systems to provide our medical professionals with enhanced means of accessing members' health information, and developing new means to permit our members to get health care services on-line. The effectiveness of our health care system is therefore highly dependent on historical information about patients and members – their medical history, their medications, and their lab results.

There is no way that a health plan can go back and secure the written consents of deceased members. Moreover, it is improbable that a health plan can secure written

consents from former members with whom they no longer have any means of communicating. (See attached illustration of the low rates of success predicted for various means of obtaining HIPAA consent from former members). At the same time the information a provider or plan maintains on their patients and members, including former members, is essential for day-to-day functions such as quality assurance (Did patients who took a certain drug experience higher rates of liver failure?) and provider credentialing (Were there repeated occurrences of certain medical problems involving a specific medical professional or health care facility?).

Resource considerations

For current and former members, obtaining consent will require significant resources, in terms of both dollars and staff time. For example, assuming we mail the consent forms, postage alone for the initial mailing to every current and former member would amount to approximately 14 million dollars. This figure does not include other mailing supplies and staff handling time to accomplish the task.

Preventing All Uses and Disclosures for Patients Without HIPAA Consent Requires Enormous and Costly Changes to Potentially Thousands of Information Technology Systems

Many information technology systems are used in the course of health care, even for routine medical office visits. For example, assume Mrs. Jones comes in for an appointment. The visit by Mrs. Jones with her doctor is usually preceded by a call to an appointment and advice call center, whose staff make notes on the call in an advice documentation system and make the appointment in a scheduling system. Mrs. Jones is logged in a registration system at the visit check-in, then a progress note by her doctor is made in her paper chart or electronic medical record. Orders are placed in order-entry systems for Mrs. Jones' lab tests and diagnostic imaging scans. The results of her labs and scan are recorded in their own systems. Her prescriptions are also ordered in a system, and a record of the dispensed medications is placed in the pharmacy system. Mrs. Jones' doctor may request a consultation through an e-mail to another Kaiser Permanente physician. Some durable medical equipment is ordered for her and recorded in the materials management system. If Mrs. Jones revoked her HIPAA consent, access to any of the parts of her record should be blocked. For information collected for one visit, blocks would need to be placed in Mrs. Jones' record in at least ten different information systems. The number of systems utilized for a hospital admission could easily be higher.

Every revocation of HIPAA consent would require checking whether there is stored protected health information on that patient in every one of Kaiser Permanente's dozens of systems in each of its regions and blockage of all uses and disclosures. The cost of implementing this requirement by changing all information technology systems and the ongoing manual maintenance of records is staggering.

Health Care Operations and Reporting to Regulatory and Accrediting Agencies is Blocked by the HIPAA Consent Requirements

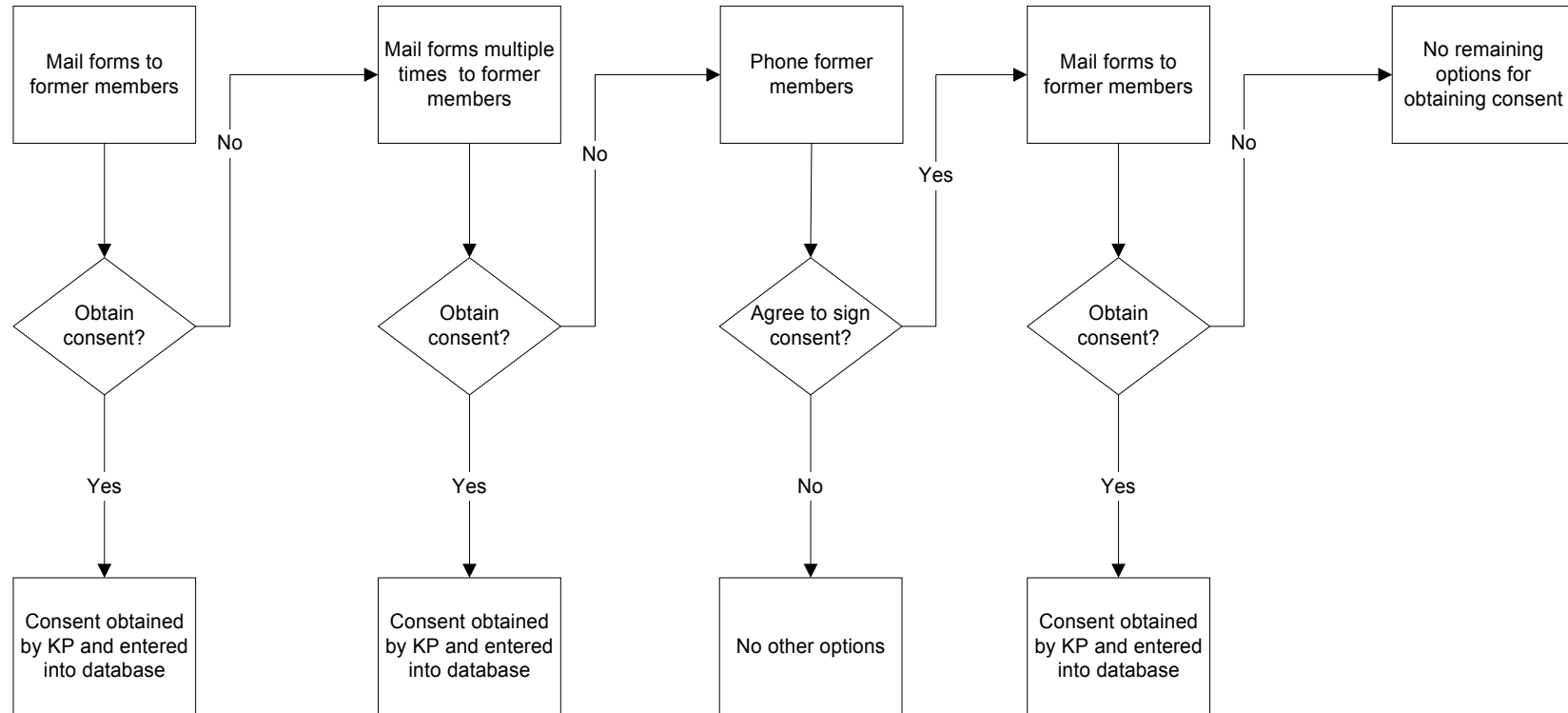
To provide Medicare services, it is necessary to use data from the past four or five years to plan for upcoming coverage years. That data includes both current and former members, some of whom are deceased or who have secured coverage elsewhere. It is essential for continuing and future members for the plan to use that information to determine what kind of facilities are likely to be necessary, what kinds of diseases and treatments need to be considered, and the number and kinds of physicians and other health care providers to whom members will need access. Such planning would be hindered when data is skewed by the removal of records of members who have not yet consented or who have revoked HIPAA consent.

NCQA and JCAHO accreditation requires that these bodies have access to a random sample of charts to determine whether quality standards are being adhered to. This sort of review could no longer be random because it could not include data for members who have not yet consented or who have revoked consent. JCAHO accreditation involves required reporting of hospital services containing protected health information that would be incomplete if patients who had revoked their HIPAA consent are excluded.

Health plans participating in the Medicare + Choice program are required to report HEDIS performance measures to NCQA. This requirement poses unique problems and potentially deleterious consequences for data quality and integrity when a member revokes HIPAA consent for treatment, payment and health care operations. For instance, when reporting the percentage of our female membership who has received a Pap Smear, how could Kaiser Permanente guarantee accurate, statistically valid data if members revoke HIPAA consent and thus disallow use and disclosure of that part of their record?

Obtaining consent for former members

Former members' PHI is an invaluable component for providing health care services to our members. Mail and phone are the only options for contacting members to obtain their consent. We believe the yield would be very low.



Rate of success: Low
1. Response rate to mailed requests will be low
a. Some former members are deceased
b. Living former members have no incentive to respond
c. Members will have moved and addresses in our database incorrect
2. Mailing costs high due to mailings to each member

Rate of success: Very low
1. Already low response rate from first mailing will only be lower
a. Low yield from those who did not respond to the first mailing
b. Repeat mailings to bad addresses
2. Return on investment very low

Rate of success: Low
1. We will have incorrect phone numbers for former members who have moved or changed phone numbers
2. Some former members will feel harassed by this point and be less inclined to re-join the plan in the future
3. Some individuals will agree on the phone to sign with no intention of doing so

Rate of success: Low
1. Some individuals will agree on the phone to sign but not return mailed forms

Resulting rate of success expected to be very low